Policy and requirement on estimation of uncertainty measurement and traceability

1. Purpose

This policy and requirements is intended to explain how to accept the estimation of uncertainty measurement and traceability. It is intended for all BLQS's staffs and assessors for their decision making on the acceptance of evaluation an uncertainty for testing and calibration results during the assessment of medical and public health laboratories accreditation comply with ISO 15189, ISO/IEC 17025 and ISO 17034 : 2016 : General requirement for the competence of reference material producer.

2. Application

This policy covers both the accredited laboratories and for those laboratories seeking accreditation to ISO 15189, ISO/IEC 17025 and ISO 17034 These requirements apply only to those tests and calibrations that are included in the scope (or proposed scope) of accreditation.

3. References

- 3.1 IUPAC Technical Report (2011) – Metrological Traceability of measurement results in Chemistry : Concepts and implementation
- 3.2 ILAC G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 – under revision
- 3.3 ILAC G24:2007 Guidelines for the determination of calibration intervals of measuring instruments – under revision

3.4 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM,3rd edition JCGM 200:2012 (JCGM 200:2008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99 : 2007 available from ISO

3.5 ISO 15189 : 2012 : Medical laboratories - Requirements for quality and competence.

- 3.6 ISO/IEC 17025 : 2017 General requirements for the competence of testing and calibration laboratories

3.7 ISO 17034 : 2016 : General requirement for the competence of reference material producer.

3.8 ILAC-P10:01/2013 : ILAC Policy on Traceability of Measurement Results.

- 3.9 JCGM 100:2008 : Evaluation of measurement data-Guide to expression of uncertainty in measurement

3.10 ISO/IEC GUIDE 98-3:2008 [JCGM/WG1/100] Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)

☞ 3.11 ISO/IEC GUIDE 98-4:2012 [JCGM 106] Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment

☞ 3.12 ISO/TS 19036:2006(en) Microbiology of food and animal feeding stuffs — Guidelines for the estimation of measurement uncertainty for quantitative determinations

☞ 3.13 Appendix J:AOAC International Methods Committee Guidelines for Validation of Microbiological Methods for food and Environmental surfaces, 2016

3.14 ISO/TS 19036:(E): Guidelines for the estimation of measurement uncertainty for quantitative determinations. 2006/Amd 1 :2009

3.15 ILAC P14:01/ 2013 : Policy for Uncertainty in Calibration

4. Definition and Abbreviation

4.1 Metrological traceability (VIM 3 clause 2.41)

Property of a measurement result where by the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Note 1 clause 2.41 states that a 'reference' can be a "definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard."

4.2 Metrological traceability chain, (VIM 3 clause 2.4.2)

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference

4.3 Metrological traceability to a measurement unit, (VIM 3 Clause 2.43)

Metrological traceability where the reference is the definition of a measurement unit through its practical realization

Note1: The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

4.4 National Metrology Institute, NMI

National Metrology Institutes (NMI) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institutes.

4.5 JCTLM The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine

5. Policy and Requirements

5.1 Policy

5.1.1 The degree of rigor or/and the need for reporting of uncertainty of measurement depends on the following:

1) the requirements of the customer;

2) the requirements of the test method;

3) the existence of narrow limits on which decisions on conformance to specification are based.

5.1.2 A testing laboratory performing its own calibrations shall have and shall apply a procedure to estimate the uncertainty of measurement

5.2 Requirements

☞ 5.2.1 **Traceability** (as given in both IUPAC and VIM) is characterized by:

1) an unbroken chain of comparisons going back to stated references acceptable to the parties, usually a national or international standard;
2) uncertainty of measurement; the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated;
3) documentation; each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be recorded;
4) competence; the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited);
5) reference to SI units; the chain of comparisons must, where possible, end at primary standards for the realization of the SI units;

6) Calibration intervals; calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment).

5.2.2 Estimating of measurement uncertainty

5.2.2.1 Medical Laboratory Testing Should be performed in accordance with ISO 15189

5.2.2.1.1 Estimating of measurement uncertainty for methods that are reported on a quantitative basis should calculate by two sources, at least

1) Internal Quality Control :

A minimum of six months data is recommended. For new methods, a minimum of 30 replicate determinations of appropriate control or reference material is required to calculate an interim standard deviation (SD).

2) Calibrator

5.2.2.1.2 Qualitative test must show its performance specifications such as sensitivity, specificity, accuracy, precision, detection limit.

5.2.2.1.3 Measurement uncertainty approach requires that known bias and systemic error are eliminated or minimized. Measurement uncertainty shall be done with

1) Pre-examination procedures: sample collection and transportation
2) Examination procedures: Follow with standard operating procedure or work instruction manual, verifying the required measurement accuracy and the functioning of the measuring system at defined intervals, technical competence.
3) Post-examination procedures: the results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures

5.2.2.1.4 Estimating of measurement uncertainty

1) Define source of uncertainty such as IQC, calibrator.
2) Evaluate standard uncertainty (SU) such as IQC = Standard deviation (SD), Calibrator = Uncertainty ÷ Divisor

3) Determine relative standard uncertainty (RSU) = Standard uncertainty (SU) ÷ Concentration
4) Determine combined relative standard uncertainty (U_C) = $\sqrt{(RSU_{IQC})^2 + (RSU_{Cal})^2}$
5) Determine expanded uncertainty (U) = k x U_C , Coverage factor (k) = 2
6) Determine expanded uncertainty of results (U_R) = Result x Expanded uncertainty (U)
7) Report = Result ± U_R

Table 1 Estimating of measurement uncertainty.

	Factor	**Value (Concentration)**	**Value of the Uncertainty or Std. Deviation**	**Divisor**	**Std.Uncertainty (SU)**	**Relative Std. Uncertainty (RSU)**
U_{IQC}	Standard deviation inter-assay		Std. Deviation $\frac{\sqrt{\sum(x-\bar{x})^2}}{n-1}$	1	Std. Deviation	SU ÷ Concentration
U_{Cal}	Uncertainty of calibrator		Specified in certificate	Specified in certificate	Uncertainty ÷ Divisor	SU ÷ Concentration
U_C	Combined relative standard uncertainty	$U_C = \sqrt{(RSU_{IQC})^2 + (RSU_{Cal})^2}$				
U_X	Expand relative standard uncertainty	U_X = k x U_C Coverage factor (k) = 2				
U_R	Expanded uncertainty of result	U_R = Conc. x U			Report Result = Conc. ± U_R	

Table 2 Example for estimating of measurement uncertainty.

	Factor	Value (Concentration)	Value of the Standard Deviation or Uncertainty	Divisor	Std. Uncertainty (SU)	Relative Std. Uncertainty (RSU)
U_{IQC}	Standard deviation inter-assay	99 mg/dl	0.9 mg/dl	1	0.9 mg/dl	0.0091
U_{Cal}	Uncertainty of calibrator	167 mg/dl	2.17 mg/dl	2	1.085 mg/dl	0.0065
U_C	Combined relative standard uncertainty	$U_C = \sqrt{(0.0091)^2 + (0.0065)^2} = 0.0112$				
U_X	Expand relative standard uncertainty	Coverage factor(k) = 2 $U_X = 2 \times 0.0112 = 0.0224$				
U_R	Expand uncertainty x conc. analysis	If the glucose in sample is 90 mg/dl $U_R = 90 \times 0.0224 = 2.02$ mg/dl			Report Result = 90 ± 2.02 mg/dl	

Note: Total Allowable Error for Medical laboratories refer to Desirable Specification for Total Error, Imprecision, and Bias, derived from intra-and inter-individual biologic variation from http://www.westgard.com/biodatabase1.htm

Table 3 Divisor a number associated with the assumed probability distribution

Distribution	Divisor	Data
Normal (k=2)	2	The uncertainty in the confidence level of 95%.
Rectangular	$\sqrt{3}$	The certificate from the manufacturer, Specification of equipment.
Triangular	$\sqrt{6}$	Tolerance of glassware by volume.
U-shape	$\sqrt{2}$	The deviation of amount of environmental.

5.2.2.2 Public Health Laboratory Testing should be performed in accordance with ISO/IEC 17025: 2017 clause 7.6

5.2.2.2.1 Physical testing

For physical testing, calibration procedure and estimation of uncertainty of testing instrument shall be applied. Physical measurements and obligated to be done with a calibrated reference instrument which by itself should be calibrated against the National Standard or other international Reference Standard issued by accredited party or a National Metrology Institute. The certificate issued by other calibration body shall contain estimation of uncertainty of measurement results.

5.2.2.2.2 Chemical testing

Chemical measurement, likewise, are obligated, where appropriate, to estimate uncertainty of measurements. For quantitative chemical testing, reasonable estimation of uncertainty procedure shall be applied based on the international standard i.e. EURACHEM/CITAC Guild, UROLAB, UKAS

The method shall have specified reporting precision/accuracy and relate the values of their measurement to reference materials by the organization traceable to international standards or traceable to a certified reference material (CRM) i.e. NIST, USP, LGC, Accredited RMP in accordance with ISO/IEC 10734 Available results from proficiency testing or interrogatory comparison may provider a reasonable estimate of the uncertainty.

5.2.2.2.3 Microbiological testing

There are both qualitative and quantitative in microbiological testing. Estimation of uncertainty of measurement is not possible in qualitative testing, laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation. Previous validation data can be a support. The standard strains or reference strains that using in testing shall be traceable to the national or international levels. Microbiological laboratories may not have report uncertainty unless required by customers or unless the interpretation of results may be compromised without it

When reporting uncertainty, a description of the procedure used the estimate the uncertainty should also be included. Estimation of uncertainty procedure shall be applied based on AOAC (2016) Appendixes and the international standard i.e. ISO/TS 19036:2006/Amd 1:2009

5.2.3 Traceability for reference materials producer which is accredited according to ISO 17034 should be complied with ILAC policy as follows:

5.2.3.1 The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO 17034, are considered to have established valid traceability.

5.2.3.2 The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

5.2.3.3 The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory shall demonstrate that each RM or CRM is suitable for its intended use as required by ISO/IEC 17025 or ISO 15189

6. History of Change

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
00	Initial Document	Miss Natamol Tienmanee	
07	- Page 1/7 Edited the reference to current APLAC TC 005 Issue No. 4, 09/10 : Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing - Page 1/7 Add Clause 5.2.2.2.3 Microbiological testing	Miss Natamol Tienmanee	22 September 2014
08	- Page 1/10 Edited the reference to current APLAC TC 010 Issue No. 2, 09/10 : General Information on Uncertainty of Measurement - Page 1/10 Edited the reference to current ISO 15189: 2012 Medical laboratories - Requirements for quality and competence.	Miss Sirimas Khamsai	28 October 2016
09	-Page 1/10 Edited the reference to current ISO 17034 : 2016 : General requirement for the competence of reference material producer.	Miss Sirimas Khamsai	19 February 2018
10	-Page 1/12 Edited the reference to current ISO/IEC17025 : 2017 General requirements for the competence of testing and calibration laboratories -Page 1/10 added the reference - IUPAC Technical Report (2011) –	Miss Sirimas Khamsai	

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
	Metrological Traceability of measurement results in Chemistry : Concepts and implementation - ILAC G17:_2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025 – under revision, - ILAC G24:_2007 Guidelines for the determination of calibration intervals of measuring instruments – under revision - JCGM 100: 2008 : Evaluation of measurement data-Guide to expression of uncertainty in measurement -Page 2/12 added the reference - ISO/IEC GUIDE 98-4:2012 [JCGM 106] Uncertainty of measurement — Part 4: Role of measurement uncertainty in conformity assessment -ISO/TS 19036:2006(en) Microbiology of food and animal feeding stuffs — Guidelines for the estimation of measurement uncertainty for quantitative determinations - Appendix J: AOAC International Methods Committee Guidelines for Validation of Microbiological Methods		

Revision No.	Documentation Changes	Prepared/Revised by	Date Issued
	for food and Environmental surfaces, 2016 -Page 3/12 - clause 5.2.1 **Traceability** (as given in both ILAC G2 and VIM) edited to **Traceability** (as given in both IUPAC and VIM) -Page 7/12 edited - clause 5.2.2.2 ISO/IEC 17025: 2017 clause 5.6.2.2.1 and 5.6.2.2.2 edited to ISO/IEC 17025: 2017 clause 7.6 - clause 5.2.2.2.2 Chemical testing edited NATA and added EURACHEM/CITAC Guild, UROLAB, UKAS -added Accredited RMP in accordance with ISO/IEC 10734 -Page 8/12 edited - based on APLAC TC 005: Interpretation and Guidance on the Estimation of Uncertainty of Measurement and added based on AOAC (2016) Appendixes - clause 5.2.3 ISO guide 34 edited to ISO 17034		

7. Data record and Used document

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Controlled copy list

1 Direct Bureau of Laboratory Quality Standards (BLQS)	No. 07 00
2 Head Laboratory Accreditation Section 1	No. 07 03
3 Head Laboratory Accreditation Section 2	No. 07 04
4 QCC / Quality Manager	No. QM 007
5 Miss Sirimas Khamsai	